

Date of Approval Letter: NOV 24 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-841

IVOMEC (Ivermectin) Pour-On for Cattle

To add persistent effect periods for 3 additional parasite species and extend the period of persistent effect for 3 existing parasite species.

**Sponsored by:
Merial Ltd.**

FOI 31

IVOMEC (ivermectin) Pour-On

1. GENERAL INFORMATION

- A. File Number: NADA 140-841
- B. Sponsor: Merial Ltd.
3239 Satellite Blvd., Bldg. 500
Duluth, GA 30096-4640

Drug Labeler Code: 050604
- C. Established Name: Ivermectin
- D. Proprietary Name: IVOMEC (ivermectin) Pour-On for Cattle
- E. Dosage Form: Topical solution
- F. How Supplied: 250-mL, 1-liter, 2.5-liter, 5-liter, and 20-liter containers
- G. How Dispensed: Over-the-Counter (OTC)
- H. Amount of Active Ingredients: 5 mg ivermectin/mL
- I. Route of Administration: Topical application along the topline extending from the withers to the tailhead
- J. Species/Class: Cattle
- K. Recommended Dosage: 1 mL for each 22 pound body weight to provide 500 mcg ivermectin/kg body weight
- L. Pharmacological Category: Antiparasitic
- M. Indications: For the effective treatment and control of these parasites.

Gastrointestinal Roundworms

- | | |
|--|------------------------------|
| <i>Ostertagia ostertagi</i>
(including inhibited stage) | (adults and L ₄) |
| <i>Haemonchus placei</i> | (adults and L ₄) |
| <i>Trichostrongylus axei</i> | (adults and L ₄) |
| <i>T. colubriformis</i> | (adults and L ₄) |
| <i>Cooperia oncophora</i> | (adults and L ₄) |
| <i>Cooperia punctata</i> | (adults and L ₄) |
| <i>Cooperia surnabada</i> | (adults and L ₄) |
| <i>Strongyloides papillosus</i> | (adults) |
| <i>Oesophagostomum radiatum</i> | (adults and L ₄) |
| <i>Trichuris</i> spp. | (adults) |

Lungworms

Dictyocaulus viviparus (adults and L₄)
Cattle Grubs (parasitic stages)

Hypoderma bovis
H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli
Haematopinus euryesternus
Damalinia bovis
Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

IVOMEC Pour-On has been proved to effectively control infections and protects cattle against reinfection with: *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing.

- n. Effect of Supplement: To add the new persistent activity indications for *Dictyocaulus viviparus* for 28 days after treatment, *Cooperia surnabada* for 14 days after treatment, and *Damalinia bovis* for 56 days after treatment. To extend the persistent activity periods for *Oesophagostomum radiatum* from 14 to 28 days after treatment and *Cooperia punctata* and *Trichostrongylus axei* from 14 days to 21 days after treatment. At this time, the labeling is being revised to reflect updated environmental information, to speciate *Cooperia* spp in the treatment and control section of the indications, and to add the veal calf warning statement to the residue information section.

2. EFFECTIVENESS

A. Dose Characterization

Effectiveness studies were presented in the original NADA 140-841 FOI Summary dated December 7, 1990, establishing the recommended effective dose of IVOMEC Pour-On for the treatment and control of internal and external parasites.

B. Substantial Evidence for Persistent Effectiveness Against Endoparasites

Five pivotal studies were conducted in the United States to evaluate the persistent activity of IVOMEC Pour-On in preventing infection of treated cattle with third stage larvae of several species of endoparasites. The studies had similar designs with separate groups of cattle receiving a daily challenge of third-stage nematode larvae 15, 21, or 28 days following treatment with ivermectin administered in its final formulation at a dose level of 0.5 mg/kg body weight. The efficacy was determined by comparing the geometric mean worm counts of the treated groups with those of an untreated control group for each parasite species present in at least six adequately infected control animals. P-values were computed for each parasite species using contrasts in a one-way analysis of variance or unequal-variance t-tests on log-transformed counts. The period of persistent activity was defined as the time during which the efficacy against a genus species was $\geq 90\%$.

For an indication to be granted, a minimum of two studies showing 90% efficacy was required for each genus species of parasite and at each persistent effect period. The new indication of persistent effect against *Dictyocaulus viviparus* for 28 days after treatment is supported by Trial ASR 15090 and Trial ASR 15095. The new indication for persistent effect against *Cooperia surnabada* for 14 days after treatment is supported by Trial ASR 14553 and Trial ASR 15110. The extension of the persistent effect period for *Oesophagostomum radiatum* from 14 days to 28 days is supported by Trial ASR 15110 and Trial ASR 15111. The extension of the persistent effect period for *Cooperia punctata* from 14 days to 21 days is supported by Trial ASR 15110 and Trial ASR 15111. The extension of the persistent effect period for *Trichostrongylus axei* from 14 days to 21 days is supported by Trial ASR 15110 and Trial ASR 15111. The five trials are individually summarized below.

B.1 Trial ASR 14553

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator: Bruce N. Kunkle, D.V.M., M.S., Ph.D.
Merial Limited
Fulton, Missouri
- 3) General Design:

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- a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
 - b. Animals: Twenty-eight (28) crossbred female and castrated male calves (7 per group), approximately 6 months old and weighing 152 to 221 kg at the start of the study were used. All animals were treated with another anthelmintic during the acclimation period to eliminate existing infections.
 - c. Treatment Groups: There were 4 treatment groups. One group received IVOMEC Pour-On. The negative controls received no treatment. Two groups received medications which were not pertinent to this approval and are not reported.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Cooperia* spp. (1000 per day for 15 days). There were larvae of other genus species given for various lengths of time that are not pertinent to this approval and are not reported. This study provided support for the 14-day persistent effect period, even though the larvae were administered for 15 days.
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - f. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 49 to 51 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 to 51 days after treatment, 35 to 37 days after the last *Cooperia* spp. larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for 3 species of *Cooperia*. Efficacy is summarized in Table 2.1:

Table 2.1 Trial ASR 14553 - Percent Efficacy IVOMEC Pour-On 15-day Persistent Effect Period

Nematode Species	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
<i>Cooperia oncophora</i>	223.3	0.5	99.8
<i>Cooperia punctata</i>	2949.8	0.5	99.9
<i>Cooperia surnabada</i>	154.2	0.5	99.6

- 5) Adverse Reactions: Some animals had loose stools during the trial and one animal vomited. These problems were not believed to be related to the experimental treatments.

B.2 Trial ASR 15090

- 1) Type of Study: Dose confirmation study in cattle with induced infections of lungworms.
- 2) Investigator: Edward G. Johnson, D.V.M.
Johnson Research
Parma, Idaho
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of lungworms are controlled.
 - b. Animals: Forty (40) Holstein intact male calves (10 per group), no more than 8 months old and weighing 183 to 278 kg at the start of the study were used. Animals were free of patent infections at the time of treatment.
 - c. Treatment Groups: There were 4 treatment groups. Two groups received IVOMEC Pour-On. Two groups were negative controls that received the vehicle for IVOMEC Pour-On topically at 1 mL/10 kg body weight.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day after treatment, according to the following schedule: *Dictyocaulus viviparus* (50 per day for 21 or 28 days). There was a separate control and treated group for each time period.
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - f. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 42 or 49 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 42 days after treatment for the 21 day period or 49 days after treatment for the 28 day period, 21 days after the last *Dictyocaulus viviparus* larvae were administered for each group.
- 4) Results: There was an adequate level of infection in at least 6 control animals for both time periods. Efficacy is summarized in Table 2.2:

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Table 2.2 Trial ASR 15090 - Percent Efficacy IVOMEC Pour-On Against *Dictyocaulus viviparus*

Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
21 days	34.5	0	100
28 days	23.3	0.1	99.4

- 5) Adverse Reactions: An injured left hind leg, pinkeye, elevated temperature, dyspnea, and bloat were observed in some animals during the trial. These health problems were not believed to be related to the experimental treatments.

B.3 Trial ASR 15095

- 1) Type of Study: Dose confirmation study in cattle with induced infections of lungworms.
- 2) Investigator: Bruce N. Kunkle, D.V.M., M.S., Ph.D.
Merial Limited
Fulton, Missouri
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of lungworms are controlled.
 - b. Animals: Twenty (20) Holstein castrated male calves (10 per group), approximately 5 to 10 months old and weighing 195 to 304 kg at the start of the study were used. Animals were free of patent infections at the time of treatment.
 - c. Treatment Groups: There were 2 treatment groups. One group received IVOMEC Pour-On and the other group was a negative control that received the vehicle for IVOMEC Pour-On topically at 1 mL/10 kg body weight.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Dictyocaulus viviparus* (100 per day for 28 days).
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - f. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 9 days after treatment.

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- i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 days after treatment, 21 days after the last *Dictyocaulus viviparus* larvae were administered.
- 4) Results: There was an adequate level of infection in 9 of the control animals. Efficacy is summarized in Table 2.3:

Table 2.3 Trial ASR 15095 - Percent Efficacy IVOMEC Pour-On Against *Dictyocaulus viviparus*

Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
28 days	15.7	0	100

- 5) Adverse Reactions: Inappetence, loose stool, depression, and a watering right eye were observed in some animals during the trial. These health problems were bit believed to be related to the experimental treatments.

B.4 Trial ASR 15110

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator: Edward G. Johnson, D.V.M.
Johnson Research
Parma, Idaho
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
 - b. Animals: Thirty (30) Holstein male calves (10 per group), approximately 4 to 12 months old and weighing 130 to 186 kg at the start of the study were used. Animals were clear of patent infections at the time of treatment.
 - c. Treatment Groups: There were 3 treatment groups. One group received IVOMEC Pour-On. The negative controls received no treatment. One group received a medication which is not pertinent to this approval and is not reported.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Cooperia oncophora* & *punctata* (1000 per day for 21 days), *Trichostrongylus axei* (500 per day for 21 days), and *Oesophagostomum radiatum* (100 per day for 28 days). There were larvae of

other genus species given for various lengths of time that are not pertinent to this approval and are not reported.

- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - g. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 49 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 days after treatment, 28 days after the last *Cooperia* spp. and *T. axei* larvae and 21 days after the last *O. radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for *C. punctata*, *C. surnabada*, *T. axei*, and *O. radiatum*. Efficacy is summarized in Table 2.4:

Table 2.4 Trial ASR 15110 - Percent Efficacy IVOMEC Pour-On 21-day or 28-day persistent effect periods

Nematode Species	Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
<i>C. punctata</i>	21	1470.7	27.0	98.2
<i>C. surnabada</i>	21	258.7	15.0	94.2
<i>T. axei</i>	21	588.7	29.1	95.1
<i>O. radiatum</i>	28	278.8	18.0	93.4

- 5) Adverse Reactions: One animal was found to have subacute pneumonia at necropsy. This health problem was not believed to be related to the experimental treatments.

B.5 Trial ASR 15111

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator: Bruce N. Kunkle, D.V.M., M.S., Ph.D.
Merial Limited
Fulton, Missouri
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.

- b. Animals: Thirty (30) Holstein heifer calves (10 per group), approximately 5 to 6 months old and weighing 165 to 268 kg at the start of the study were used. Animals were free of patent infections at the time of infection.
 - c. Treatment Groups: There were 3 treatment groups. One group received IVOMEC Pour-On. The negative controls received no treatment. One group received a medication which was not pertinent to this approval and is not reported.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Cooperia punctata* (1000 per day for 21 days), *Trichostrongylus axei* (500 per day for 21 days), and *Oesophagostomum radiatum* (100 per day for 28 days). There were larvae of other genus species given for various lengths of time that were not pertinent to this approval and are not reported.
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - h. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 49 or 50 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 or 50 days after treatment, 28 or 29 days after the last *Cooperia* spp. and *T. axei* larvae and 21 days after the last *O. radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for *C. punctata*, *T. axei*, and *O. radiatum*. Efficacy is summarized in Table 2.5:

Table 2.5 Trial ASR 15111 - Percent Efficacy IVOMEC Pour-On 21-day or 28-day persistent effect periods

Nematode Species	Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
<i>C. punctata</i>	21	2917.8	1.8	99.9
<i>T. axei</i>	21	2122.8	1.5	99.9
<i>O. radiatum</i>	28	174.2	1.7	99.0

- 5) Adverse Reactions: Soft stool, bloody stool, abdominal swelling, nasal discharge, depressed appetite, and elevated temperature were observed in three nonmedicated control animals during the trial. These health problems were not believed to be related to the experimental treatments.

C. Substantial Evidence for Persistent Effectiveness Against *Damalinia bovis*

Two pivotal studies were conducted in the United States to evaluate the persistent activity of IVOMEC Pour-On in preventing infestation of treated cattle with *Damalinia bovis*. The studies had similar designs with separate groups of lice-free cattle being exposed to infested cattle for either 42 to 49 days after treatment or 49 to 56 days after treatment with ivermectin administered in its final formulation at a dose level of 0.5 mg/kg body weight. The efficacy was determined by comparing the geometric mean lice counts of the treated groups with those of an untreated control group on two separate count days post introduction of infested cattle. An adequate level of infestation had to be present in at least six infested control animals in order for the study to be acceptable. Lice counts were transformed to the natural logarithm (count + 1) for calculation of the geometric means. Treated and control groups were compared at each post-treatment time point using Wilcoxon's rank sum test. The period of persistent activity was defined as the time during which the efficacy against lice was demonstrated to be $\geq 90\%$.

For an indication to be granted, a minimum of two studies showing 90% efficacy was required at each persistent effect period. The new indication of persistent effect against *Damalinia bovis* for 56 days after treatment is supported by Trial Number PR&D 0045401 and Trial Number PR&D 0045402. The two trials are individually summarized below.

C.1 Trial Number PR&D 0045401

- 1) Type of Study: Dose confirmation study in cattle with natural infestations of lice.
- 2) Investigator: K.E. Sterner, B.S., D.V.M.
Sterner Veterinary Clinic
Ionia, Missouri
- 3) General Design:
 - a. Purpose: To evaluate the persistence of effect of topically administered ivermectin at 500 mcg/kg body weight to prevent the establishment of lice (*Damalinia bovis*) by natural transfer.
 - b. Animals: Thirty (30) louse-free female Holstein calves, approximately 6 months old and weighing 119 to 244 kg on Day -1 were used as principle animals. Thirty (30) female and male castrate Holstein or Holstein crossbred calves, weighing 124 to 243 kg on Day 48 were used as donor animals. To ensure the principle animals were free of lice, they were treated topically with Vapona spray on Days -19 and -5 according to the manufacturer's recommendations and were free of lice as confirmed by a pretreatment examination on Day 0.

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- c. Treatment Groups: There were 3 treatment groups. Two groups received IVOMEC Pour-On, one on Day 0 and the other on Day 7. The negative control group received a placebo vehicle that resembled the appearance of the test drug.
 - d. Infestation: Each principal animal was naturally infested by exposure to donor cattle shown to have infestations of *Damalinia bovis*. Beginning on Day 49, each principal animal was exposed to one donor animal for 7 days. Following exposure, donor animals were removed on Day 56.
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - i. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 84 days after treatment.
 - i. Pertinent Variables Measured: Lice counts were conducted on principal animals on Days 70 and 84 to ensure sufficient time for any lice successfully transferred to become established. These counts at each time point were calculated for each animal by summing the counts from 12 predilection sites.
- 4) Results: There was an adequate level of infestation in at least 6 control animals for *Damalinia bovis*. Efficacy is summarized in Table 2.6:

Table 2.6 Trial Number PR&D 0045401 - Percent Efficacy IVOMEC Pour-On Against *Damalinia bovis*

Challenge Period ¹	Count Day	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On	P-value ²
42 to 49 days	70	23.0	0.0	100	<0.0001
42 to 49 days	84	44.4	0.0	100	<0.0001
49 to 56 days	70	23.0	0.0	100	<0.0001
49 to 56 days	84	44.4	0.0	100	<0.0001

¹Days after treatment that principal animals were exposed to donor animals. Cattle treated on Day 0 were challenged 49 to 56 days after treatment and cattle treated on Day 7 were challenged on 42 to 49 days after treatment.

²The p-value represents the exact probability of a statistical difference between the treatment group and the control group using the Wilcoxin rank sum test in SAS.

- 5) Adverse Reactions: No treatment related health problems were observed.

C.2 Trial Number PR&D 0045402

- 1) Type of Study: Dose confirmation study in cattle with natural infestations of lice.
- 2) Investigator: J.E. Holste, D.V.M.
Merial Limited
Fulton, Missouri
- 3) General Design:
 - a. Purpose: To evaluate the persistence of effect of topically administered ivermectin at 500 mcg/kg body weight to prevent the establishment of lice (*Damalinia bovis*) by natural transfer.
 - b. Animals: Thirty (30) louse-free female Holstein calves, approximately 6 months old and weighing 173 to 224 kg on Day -1 were used as principle animals. Thirty (30) female and male intact and castrate Holstein or Holstein crossbred calves, weighing 91 to 257 kg on Day 48 were used as donor animals. To ensure the principal animals were free of lice, they were treated topically with Vapona spray on Days -19 and -5 according to the manufacturer's recommendations and were free of lice as confirmed by a pretreatment examination on Day 0.
 - c. Treatment Groups: There were 3 treatment groups. Two groups received IVOMEC Pour-On, one on Day 0 and the other on Day 7. The negative control group received a placebo vehicle that resembled the appearance of the test drug on Day 7.
 - d. Infestation: Each principal animal was naturally infested by exposure to donor cattle shown to have infestations of *Damalinia bovis*. Beginning on Day 49, each principal animal was exposed to one donor animal for 7 days. Following exposure, donor animals were removed on Day 56. Counts were conducted on principal animals on Days 70 and 84 to ensure sufficient time for any lice successfully transferred to become established.
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - j. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 84 days after treatment.
 - i. Pertinent Variables Measured: Lice counts conducted on principal animals on Days 70 and 84 were calculated for each animal by summing the counts from 12 predilection sites.

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- 4) Results: There was an adequate level of infestation of *Damalinia bovis* in at least 6 control animals on both count days. Efficacy is summarized in Table 2.7:

Table 2.7 Trial Number PR&D 0045402 - Percent Efficacy IVOMEC Pour-On Against *Damalinia bovis*

Challenge Period ¹	Count Day	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On	P-value ²
42 to 49 days	70	133.7	0.0	100	<0.0001
42 to 49 days	84	139.1	0.0	100	<0.0001
49 to 56 days	70	133.7	0.0	100	<0.0001
49 to 56 days	84	139.1	0.0	100	<0.0001

¹Days after treatment that principal animals were exposed to donor animals. Cattle treated on Day 0 were challenged 49 to 56 days after treatment and cattle treated on Day 7 were challenged on 42 to 49 days after treatment.

²The p-value represents the exact probability of a statistical difference between the treatment group and the control group using the Wilcoxin rank sum test in SAS.

- 5) Adverse Reactions: No treatment related health problems were observed.

3. TARGET ANIMAL SAFETY

No further target animal safety data were required from the original approval as discussed in the parent NADA 140-841 FOI Summary dated December 4, 1990.

4. HUMAN SAFETY

No further human food safety data were required from the original approval as discussed in the parent NADA 140-841 FOI summary dated December 4, 1990 and in the supplement to NADA 128-409 FOI summary (IVOMEC Injection for Cattle) dated September 12, 1994. There is a 48-day withdrawal period for slaughter, a withdrawal period for milk has not been established, and a withdrawal period has not been established for pre-ruminating calves.

5. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that IVOMEC (ivermectin) Pour-On for Cattle when administered once at 500 mcg/kg body weight is safe and effective for the addition of the following new persistent effect indications: *Dictyocaulus viviparus* for 28 days, *Cooperia surnabada* for 14 days, and *Damalinia bovis* for 56 days. Also, the persistent effect periods are extended for the following: *Oesophagostomum radiatum* from 14 to 28 days and *Cooperia punctata* and *Trichostrongylus axei* from 14 days to 21 days.

IVOMEC (ivermectin) Pour-On

The following has been added to the residue information section of the labeling, "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."

The Agency has concluded that this product retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the new persistent effect indications and the extension of 3 already approved persistent effect indications listed above.

No patent information was submitted with this application.

6. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

- A. 250 mL – Leaflet front (Page 1 and 2), label front, carton
- B. 1 L – Leaflet, front and base, carton
- C. 2.5 and 5 L – Label front and back, carton
- D. 20 L – label front and back, outsert front and back (page 1 and 2)
- E. Package insert for all container sizes

← 917 →



Parasiticide

INTRODUCTION
IVOMEC (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

overmembrane is a member of the macrocyclic lactone class of compounds which have a unique mode of action. Compounds of this class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle.

INDICATIONS
VOMEC Pour-On applied at the recommended dose level of 500 mg/kg is indicated for the effective treatment and control of these parasites.

(adults and L.)
T. colubriformis
(adults and L.)
T. richmanni
(adults and L.)
T. richmanni phaseol
(including inhibited stage)
T. richmanni phaseol
(adults and L.)
T. richmanni phaseol
(adults and L.)
T. richmanni phaseol
(adults and L.)

Hypodermie bovis
H. lineatum
Mites
Sarcoptes scabiei var. *bovis*

20 Liter Pack
1575 (10/201 Pack)

equipment. Connect the dosing applicator and the draw-off tubing to the equipment. Connect the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Follow the dosing equipment manufacturer's directions for equipment use. (Minimum) 100-000. Other dosing equipment may be acceptable, resulting in looking, incorrect dosage

applicant. Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap having the draw-off tubing. Gently prime the dosing applicator, checking for leaks.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for mercurials. Based on plasma levels, the topically applied mercurials are absorbed in the skin at a rate well indicated by the following table:

WARNING
NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

MSDS or for assistance, contact Merck at 1-888-637-4251.
WARNING (FLAMMABLE)
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME,
AND OTHER SOURCES OF IGNITION.

To minimize accidental skin contact, the user should wear long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been

PRECAUTIONS

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

cloudiness in the formulation may occur when NOVMEC Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Vermetacin has been associated with adverse reactions in sensitive dogs; therefore, Vermetacin Pour-On is not recommended for use in dogs.

Note: Magenta does NOT print!

13"

Contents of this insert.

Parasiticide

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INTRODUCTION

IVOMEC (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

INDICATIONS

IVOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄)
(including inhibited stage)

Haemonchus placei (adults and L₄)

Trichostrongylus axei (adults and L₄)

T. colubriformis (adults and L₄)

Cooperia oncophora (adults and L₄)

Cooperia punctata (adults and L₄)

Cooperia sumabada (adults and L₄)

Strongylidae papillosus (adults)

Oesophagostomum radiatum (adults and L₄)

Trichuris spp. (adults)

Lungworms

Dictyocaulus viviparus (adults and L₄)

Cattle Grubs

Hypoderma bovis (parasitic stages)

H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

Lice

Lipophthalmus vituli

Haematopysyllus eurysternus

Dermatobia spp.

Solenopotes capitatus

Horn Flies

Haematobia irritans

Parasitic Activity

IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia sumabada* for 14 days after treatment; *Dermatobia* spp. for 56 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Squeeze-Measure-Pour System

(8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

Squeeze-Measure-Pour System

(33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 lb (100 kg) or 330 lb (150 kg) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

Officially Registered

doing applicator, checking for leaks.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING

NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merck at 1-888-837-4251.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., calmed mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 fl oz/2.5 L or 169 fl oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

IVOMEC and Cattle Head Logo are registered trademarks of Merck Limited.

Merck Limited, a company limited by shares registered in England and

Note: Mages

Copestylum punctata and *Trichostyrax* are for 21 days after treatment; *Cataglyphis* and *Heptanocryptus* are for 14 days after treatment; *Lasius* and *Formica* are for 55 days after treatment.

Treatment of cattle for Horn Flies

IVOMEC Pour-On controls horn flies (Horn Flies) for up to 28 days after dosing. For best results IVOMEC Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

DOSEAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Squeeze-Measure-Pour System

16.5 fl oz/250 mL Bottle with 25 mL Measuring Cup)

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When the correct body weight is between markings, use the higher setting. Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines. By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The Squeeze-Measure-Pour System will close the system between dosing.

Squeeze-Measure-Pour System

33.8 fl oz/1 Liter Bottle with 50 mL Measuring Cup)

Attach the measuring cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When the correct body weight is between markings, use the higher setting. Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines. By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The Squeeze-Measure-Pour System will close the system between dosing.

Collapsible Pack

16.5 fl oz/250 mL Pack and 100 fl oz/3 L Pack)

Connect the applicator gun to the collapsible pack as follows:

Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in leaking, incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap.

Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Front

Back

IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to hemecth, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal areas may cause bovine botfly larvae when it is in the ventral canal. Issues may cause stagging or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when hemecth comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free hemecth may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other hemecth, hemecth is absorbed in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 Liter bottle with a squeeze-measure-pour system, or in an 84.5 fl oz/2500 mL bottle with appropriate automatic dosing equipment.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Merial Limited, a company listed by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domesticated in Delaware, USA as Merial LLC.

U.S. Pat. 4,199,569
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Rev. 08-2003
1050-1445-OF
Duke, Georgia
30096-4640, U.S.A.

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.

FACSIMILE LABELING

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # 1050-1445-OF

Client: Ruminant Animal Global Enterprise
Originator: Bruce Somerville
Country: USA
Brand: Ivomec Pour-On
Project: Revise Persistency Activity

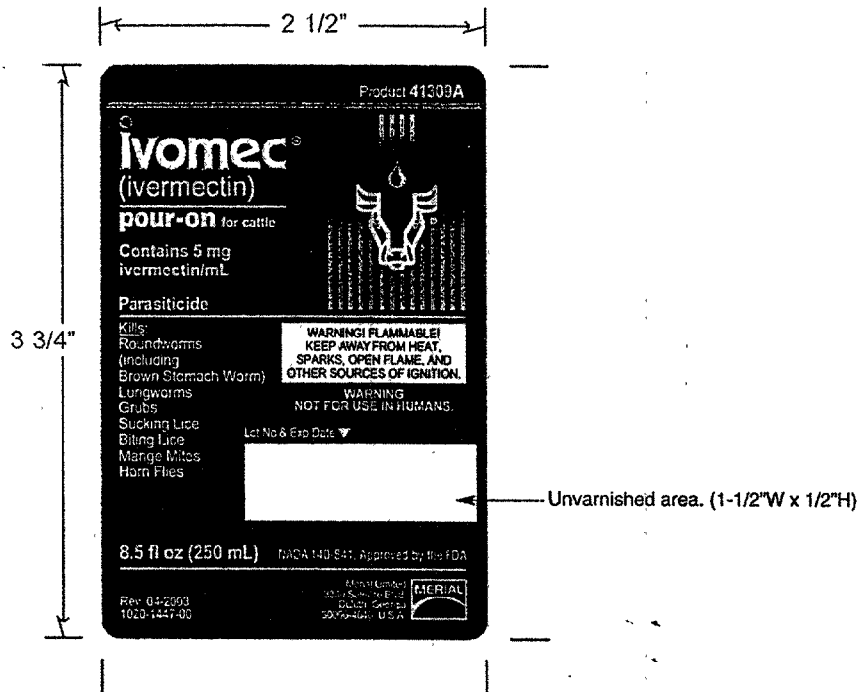
Component Description: Insert

Graphic Designer: Patricia Greene
Telephone #: (678) 638-3302
Date: 18 August 2003
Revision - Date: A - 03/10/03
B - 03/27/03
C - 03/28/03 (SM)
D - 08/15/03
Note: this revision history is for internal GPT purposes ONLY

Colors: Black Black PMS 185 Red
Use PANTONE MATCHING SYSTEM for an accurate color representation.

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.

Dieeline for Merial 250mL
Front Label
Final Label size 3 3/4" x 2 1/2"
Created 12/02



Note: Cyan callouts do NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # **1020-1447-00**

Client: Ruminant Animal Global Enterprise

Originator: Tanyja Porcha

Country: USA

Brand: Ivomec Pour-On

Project: 250mL

Component Description: Label (front)

Graphic Designer: Chandra Bulmer

Telephone #: 678-638-3261

Date: 13 June 2003

Revision - Date: A - 03/07/03

Note: this revision B - 03/26/03

history is for internal C - 04/15/03 PRD

GPT purposes ONLY D - 06/13/03 Revised PRD

Colors:

Use PANTONE MATCHING SYSTEM
for an accurate color representation.

☐ PMS 874 Gold
☐ Special Brown (c=0/m=74/y=100/k=80)
☐ PMS 185 Red
☐ Magenta
☐ Yellow

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Duluth, GA 30096, U.S.A. 

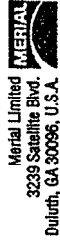
Client: Ruminant Animal Global Enterprise
 Originator: Tanyia Porcha
 Country: USA
 Brand: Ivomec Pour-On
 Project: 250mL
 Component Description: Outsert

Graphic Designer: Chandra Bulmer
 Telephone #: 678-638-3261
 Date: 15 April 2003
 Revision - Date: A - 03/07/03
 Note: this revision B - 03/26/03
 history is for internal C - 04/15/03 PRD
 GPT purposes ONLY

Colors:

Use PANTONE MATCHING SYSTEM
 for an accurate color representation.

Special Brown (c=0/m=74/y=100/k=80)
 PMS 185 Red



Cyan does NOT print

3 3/4"

3 3/4"

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS
 For the treatment and control of gastro-intestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING
 NOT FOR USE IN HUMANS.
 Keep this and all drugs out of the reach of children.

The Merial Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING: FLAMMABLE!
 KEEP AWAY FROM HEAT!
 SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

REGISTERED TRADEMARKS OF MERIAL LIMITED:
 IVOMEC and Cattle Head Logo are Made in U.S.A.
 U.S. Pat. 4,199,569

Extended Intertek® Testing Station Label
 Resealable Zipper

Page 3

Page 2

Fold Leaflet dieline along this line to view it backed up

Page 4

Leaflet Front Pg. 1

Total Leaflet Length is 3 7/8
 1 5/8" 2 1/4"

Product 41309A

Ivomec®
 (ivermectin)
pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills:
 Roundworms (including Brown Stomach Worm)
 Lungworms
 Grubs
 Sucking Lice
 Biting Lice
 Mange Mites
 Horn Flies

WARNING! FLAMMABLE!
 KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

WARNING
 NOT FOR USE IN HUMANS.

8.5 fl oz (250 mL)

NADA 140-841, Approved by the FDA

Rev. 04-2003
 1060-1446-00

Merial Limited
 3239 Satellite Blvd.
 Duluth, Georgia
 30096-4640, U.S.A.

CHNOLOGY

Component # 1030-1448-00

Chandra Bulmer
538-3261

03/10/03
03/26/03
04/15/03 PRD
06/13/03 Revised PRD

Colors:

Use PANTONE MATCHING SYSTEM
for an accurate color representation

PMS 874 Gold
Special Brown (c=0/m=74/y=100/k=80)
Black
Magenta
Yellow
PMS 185 Red

Merial Limited
3339 Satellite Blvd.
Duluth, GA 30096, U.S.A.

does NOT Print!

Product 41309A

Ivomec
(ivermectin)

pour-on for cattle
ivermectin/mL

g Brown Stomach Worm),
Sucking Lice, Biting Lice,
oses

Ivomec
(ivermectin)
pour-on for cattle

This topically applied formulation of IVOMEC® (ivermectin) achieves internal and external parasite control in one convenient, low-volume application.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect contents from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hot or hide is wet, and reduction of body may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not ingest orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32°F. Allowing to warm to room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dandruff or other skin conditions, e.g., dandruff, dandruff.

Ivermectin has been associated with adverse reactions in horses; therefore IVOMEC Pour-On is not recommended for use in equines other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved manner by incineration.



Barcode Pro 4 0 UPC-A
Symbol Width 2 45
Placed Magnification 100%
Bar x-Dimension 025
Width 1-1/4"
Height 1"
Color Black

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # **1030-1448-00**

Client: Ruminant Animal Global Enterprise
Originator: Tanyja Porcha
Country: USA
Brand: Ivomec Pour-On
Project: 250mL

Graphic Designer: Chandra Bulmer
Telephone #: 678-638-3261
Date: 13 June 2003

Revision - Date: A - 03/10/03
B - 03/26/03
C - 04/15/03 PRD
D - 06/13/03 Revised PRD
Hold this revision history as an internal GPT purposes ONLY

Component Description: Tuck Carton

Colors

Use PANTONE MATCHING SYSTEM for an accurate color representation

■ PMS 874 Gold
■ Special Brown (c=0/m=74/y=100/k=80)
■ Black
■ Magenta
■ Yellow
■ PMS 185 Red

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.

Cyan does NOT Print!

Product 41309A
8.5 fl oz (250 mL)
Contains 5 mg ivermectin/mL
Ivomec®
(ivermectin)
Pour-on for cattle

Ivomec®
(ivermectin)
Pour-on for cattle

For assistance in the diagnosis, treatment and

of gastrointestinal roundworms, including lungworms, grubs, horn flies, sucking and biting lice.

See indications and use directions

For 22 lb of body weight. The formulation should be applied in a narrow strip extending from the withers to the

the bottom of the cup to sign the correct body weight. When body weight is between 100 and 200 lb, the cap will close the

to deliver a slight excess of the required dosage.

The cap automatically adjusts to the correct level of dose. The cap (STOP) position will close the

are the registered trademarks of Merial Limited

Lot No & Exp Date ▼

Ivomec®
(ivermectin)
Pour-on for cattle

Animal Safety
Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING:
NOT FOR USE IN HUMANS.
Keep this and all drug out of the reach of children.

This product should not be applied to skin of humans because it may be irritating to human skin and eyes and absorbed through the skin to minimize accidental skin contact the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

RESIDUE INFORMATION:
Cattle must not be treated with 40 days of slaughter for human consumption. Residue should be 0.01 ppm. This has been established as a no residue withdrawal period for all animal products. A withdrawal period has not been established for the product in human consumption. Do not use in cattle to be processed for food.

Rev. 04-2003
1030-1448-00

Ivomec®
(ivermectin)

Pour-on for cattle
Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 10-550 lb Doses



NADA 140-821, Approved by the FDA

8.5 fl oz (250 mL)



Ivomec®
(ivermectin)
Pour-on for cattle

This topically applied formulation of IVOMEC® (ivermectin) delivers internal and external parasite control in one convenient low-volume application.

PRECAUTIONS
Store away from excessive heat (104°F/40°C) and protect contents from light.

Use only on well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when rain or high humidity is expected. Reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Overdose with the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Any parasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., oiled mud or manure.

Ivermectin has been associated with adverse reactions in some two days thereafter. IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.



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Color

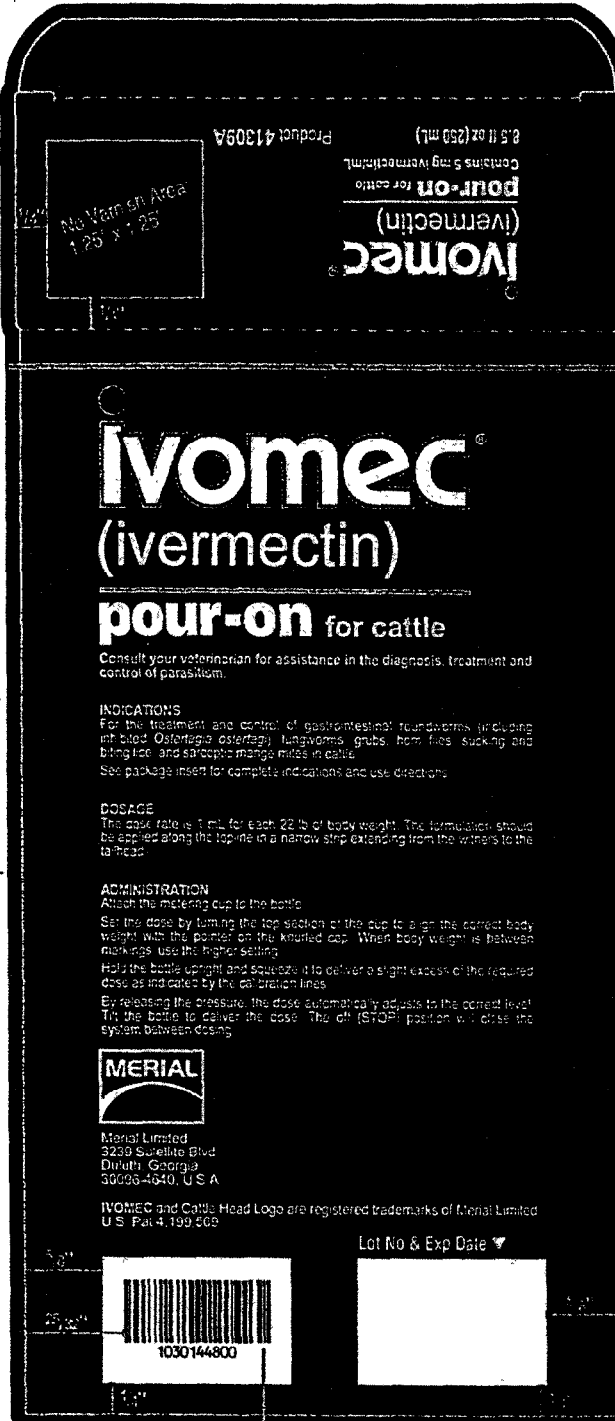
Global Maker Pro
Code: 128, C-128/1
Width: 1181
Height: 1/2
Color: Black

MERIAL GLOBAL PACKAGING

Client Rumnan Anma Goba Enterpr se
 Originator Tanya Porca
 Country USA
 Brand Ivomec Pour-On
 Project 250mL
 Component Description Tuck Carton

Graphic Design
 Telephone #
 Date 13 Ju
 Revision - 0
 Note this revision
 history is for inter-
 PT purposes only.

Cy



Ivomec® (ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gastrointestinal roundworms (including intestinal *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. In the bottle to deliver the dose. The off (STOP) position will close the system between dosing.



Merial Limited
 3230 Sufelito Blvd
 Duluth, Georgia
 30096-4640, U.S.A.

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 U.S. Pat. 4,199,009

Lot No & Exp Date ▼



Ivomec® (ivermectin) pour-on for cattle

Animal Safety

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin based on plasma levels. The topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING

NOT FOR USE IN HUMANS
 Keep this and all contents
 out of the reach of children.

This product should not be applied to skin or other exposed surfaces because it may be irritating to human skin and eyes and absorbed through the skin. To minimize these hazards, contact the user should wear a long-sleeved shirt, trousers, gloves, and shoes. If contact occurs, immediately wash with water. If accidental eye exposure occurs, immediately wash with water. Seek medical advice.

WARNING! FLAMMABLE
 KEEP AWAY FROM HEAT
 SPARKS, OPEN FLAME
 AND OTHER SOURCES
 OF IGNITION

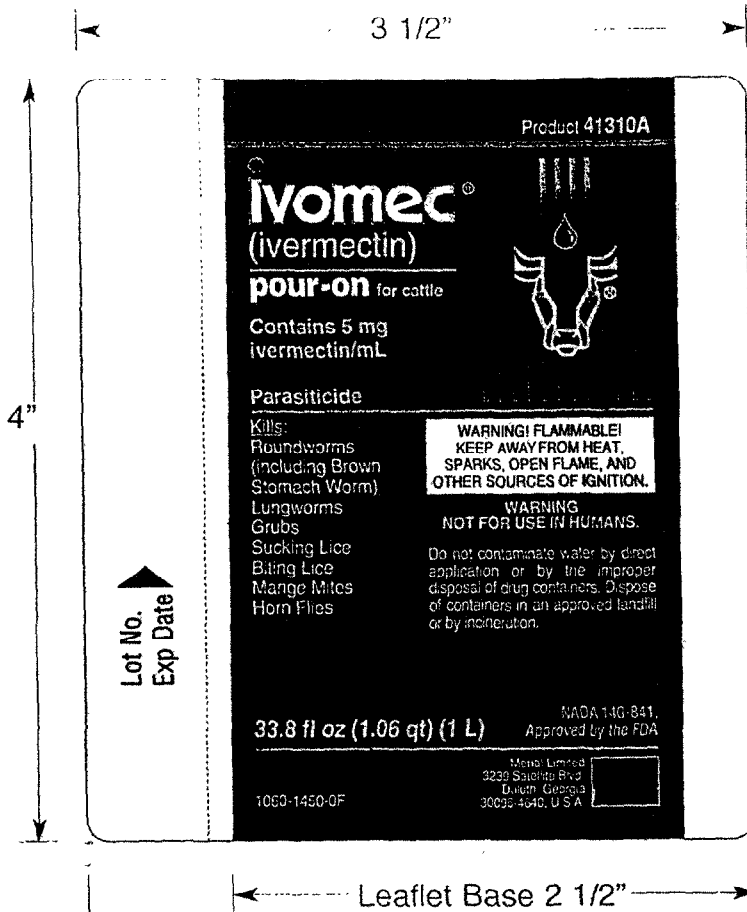
RESIDUE INFORMATION:

Cattle must not be treated with 40 days of slaughter for human consumption. Exposed carcasses must not be consumed. The residue has not been established. Do not use in horses, dairy cattle, or breeding stock. A withdrawal period has not been established for the product. Intra-muscular use: Do not use in cattle to be processed for food.

Rev. 04-2003
 1030-1448-00

8.5 FL OZ (247 mL)

Local Make Pro
 Code 128 C-128/1
 Width 1.181
 Height 1/2
 Color Black



well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING
NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children. The Material Safety Data Sheet (MSDS) contains detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Mer: 1-888-637-4251.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION

This product should not be applied to self or off because it may be irritating to human skin and eyes absorbed through the skin. To minimize accidental contact, the user should wear a long-sleeved shirt, rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental exposure occurs, flush eyes immediately with water seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS
Store away from excessive heat (104°F/40°C) and protect from light.
Use only in well-ventilated areas or outdoors.
Close container tightly when not in use.

Page 6

MERIAL GLOBAL PACKAGING TECHNOLOGY

Client: Ruminant Animal Global Enterprise
Originator: Bruce Somerville
Country: USA
Brand: Ivomec Pour-On
Project: 1 Liter (Revise Persistent Activity)

Component Description: Outsert

Graphic Designer: Patricia Greene
Telephone #: 678-638-3302
Date: 18 August 2003
Revision - Date: A - 03/28/03
Note, this revision B - 03/28/03 (SM)
history is for internal C - 08/18/03
GPT purposes ONLY

Component # **1060-1450-0F**

Colors:
Use PANTONE-MATCHING SYSTEM for an accurate color representation.

■ PMS 874 Gold
■ Special Brown (c=0/m=74/y=100/k=80)
■ Black
■ Magenta
■ Yellow
■ PMS 485 Red

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.


Facsimile Labeling

ing
of the required dose as indicated by the calibration
releasing the pressure, the dose automatically adjusts
the correct level. Fill the bottle to deliver the dose. When
0 to (10 mL) or 330 to (15 mL) dose is required, turn the
inter to "STOP" before delivering the dose. The off
TOP position will close the system between dosing.
4.5 fl oz/2.5 L Pack and 169 fl oz/5 L Pack
Insert the applicator gun to the collapsible pack as
follows:
act the open end of the draw-off tubing to the dosing
equipment. (Because of the solvents used in the
mulation, only the Protector Drench Gun from
Merial Supplies Limited, or equivalent, is
recommended. Other applicators may exhibit compatibility
problems resulting in locking, incorrect dosage or leakage.)
place the shipping cap with the draw-off cap and tighten
firm. Attach draw-off tubing to the draw-off cap.
only prime the applicator gun, checking for leaks.
follow the manufacturer's directions for adjusting the dose.
then the interval between uses of the applicator gun is
needed to exceed 12 hours. Disconnect the gun and
draw-off tubing from the product container and empty the
product from the gun and tubing back into the product
container. To prevent removal of spilled lubricants from the
applicator Drench Gun, the gun and tubing must not be
shed.
FINAL SAFETY
udies conducted in the U.S.A. have demonstrated the
safety margin for ivermectin. Based on plasma levels, the
locally applied formulation is expected to be at least as

Page 5

2 5/16"

Product 41310A



WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

WARNING!
NOT FOR USE IN HUMANS.

Do not contaminate water by direct contact or by the improper disposal of drug containers. Dispose of containers in an approved landfill.

NADA 140-841
Approved by the FDA

Merial Limited
3239 Satellite Blvd
Duluth, Georgia
30096-4640, U.S.A.

well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING
NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors. Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOVEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOVEC Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

IVOVEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOVEC Pour-On at the end of the fly season may be re-treated with IVOVEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Studies indicate soil it readily a inactive over fir and certain aqu lakes, streams c Do not contain improper dispos in an approved l

As with other av of treated anim growth of pest source of food duration of suc When used acc expected to hav dependent insect

HOW SUPPLIED
IVOVEC Pour-On 33.8 fl oz/1 L bot in an 84.5 fl oz/2.5 L container automatic dosing

Merial Limited
3239 Satellite Blvd
Duluth, Georgia
30096-4640, U.S.A.

Merial Limited, a c and Wales (registe PO Box 327, Sand Business Park, He domesticated in De

U.S. Pat 4,199,569
Copyright © 2003 I All Rights Reserve

Base 2 1/2"

Page 6

Page 7

Fold Leaflet dieline along this line to view

Page 5

Page 4

TECHNOLOGY

Designer: Patricia Greene

678-638-3302

August 2003

Date: A - 03/28/03
ion B - 03/28/03 (SM)
ternal C - 08/18/03
ONLY

ment # 1060-1450-0F

TONE-MATCHING SYSTEM
curate color representation.

PMS 874 Gold
Special Brown (c=0/m=74/y=100/k=80)
Black
Magenta
Yellow
PMS 485 Red

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically-applied formulation is expected to be at least as

ANIMAL SAFETY

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the container. To prevent removal of special lubricants from the product from the gun and tubing back into the product, draw-off tubing from the product container and empty the container. To prevent removal of special lubricants from the product from the gun and tubing back into the product, draw-off tubing from the product container and empty the container.

Follow the manufacturer's directions for adjusting the dose. Gently prime the applicator gun, checking for leaks.

Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

problems resulting in locking. Incorrect dosage or leakage.)

instrument Suppliers Limited, or equivalent, is recommended. Only the Protector Drench Gun from

equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from

Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from

Connect the applicator gun to the collapsible pack as follows:

(4.5 fl oz/2.5 L Pack and 169 fl oz/5 L Pack)

By releasing the pressure, the dose automatically adjusts excess of the required dose as indicated by the calibration

Hold the bottle upright and squeeze it to deliver a slight

setting.

When body weight is between markings, use the higher

Set the dose by turning the top section of the cup to align the

Attach the metering cup to the bottle.

(33.8 fl oz/1 L Bottle with 50 mL Metering Cup)

Squeeze-Measure-Pour System

(STOP) position will close the system between dosing.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off

lines.

Hold the bottle upright and squeeze it to deliver a slight

When body weight is between markings, use the higher

Set the dose by turning the top section of the cup to align the

Attach the metering cup to the bottle.

(4.5 fl oz/2.5 L Bottle with 25 mL Metering Cup)

Squeeze-Measure-Pour System

Administration

Formulation should be applied along the topline in a narrow

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The

effectively control

infection with

causis vitreus

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

adults and L4

2 5/16"

2 3/8"

2 3/8"

2 3/8"

2 1/2"

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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When to Treat Cattle with Grubs

IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 fl oz/2.5 L or 169 oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

Merial Limited
3239 Satellite Blvd.
Duluth, Georgia
30096-4640, U.S.A.

IVOMEC and Cattle Head
Logo are registered
trademarks of Merial Limited.

Merial Limited, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domesticated in Delaware, USA as Merial LLC.

U.S. Pat 4,199,569
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Made in U.S.A.
Rev. 06-2003

Ivomec®
(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

Kills:
Roundworms
(including Brown
Stomach Worm)
Lungworms
Grubs
Sucking Lice
Biting Lice
Mange Mites
Horn Flies

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT,
SPARKS, OPEN FLAME, AND
OTHER SOURCES OF IGNITION.

WARNING
NOT FOR USE IN HUMANS.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

33.8 fl oz (1.06 qt) (1 L)

NADA 140-811,
Approved by the FDA

1060-1450-0F

Merial Limited
3239 Satellite Blvd.
Duluth, Georgia
30096-4640, U.S.A.

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Leaflet Front Pg. 1

Fold Leaflet dieline along this line to view it backed up

Page 4

Page 3

Page 2

INDICATIONS
IVOMEC® (ivermectin) Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the treatment and control of these parasites.

Gastrointestinal Roundworms
(including liver fluke stage)
Ostertagia ostertagi
(adults and L4)

Trichostrongylus axei
(adults and L4)

Haemonchus placei
(adults and L4)

Trichostrongylus axei
(adults and L4)

T. colubriformis
(adults and L4)

Cooperia oncophora
(adults and L4)

Cooperia sunnadati
(adults and L4)

Strongylus papillosus
(adults and L4)

Cesophogostomum radiatum
(adults and L4)

Trichuris spp.
(adults and L4)

Lungworms
Dicrocoelium viverrinum
(adults and L4)

Cattle Grubs
Hypoderma bovis
(adults and L4)

Mites
Sarcoptes scabiei var. bovis
(adults and L4)

Lice
Linognathus setosus
(adults and L4)

Haematophagous mites
Dermanyssus
(adults and L4)

Horn Flies
Haematobia irritans
(adults and L4)

Persistent Activity
IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Cesophogostomum radiatum* and *Dicrocoelium viverrinum* for 28 days after treatment; *Cooperia punctata* and

ADMINISTRATION
IVOMEC Pour-On should be applied along the topline in a narrow strip extending from the withers to the tailhead. The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

DOSEAGE
The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADVERSE REACTIONS
When body weight is between markings, use the higher corrected body weight with the pointer on the knurled cap. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

HOW TO USE
Squeeze-Measure-Pour System
(8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

HOW TO USE
Squeeze-Measure-Pour System
(33.8 fl oz/1 L Bottle with 50 mL Metering Cup)
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

When body weight is between markings, use the higher corrected body weight with the pointer on the knurled cap. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

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Cooperia oncophora
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Cooperia sunnadati
(adults and L4)

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(adults and L4)

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(adults and L4)

Trichuris spp.
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Lungworms
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Cattle Grubs
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HOW TO USE
Squeeze-Measure-Pour System
(8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

HOW TO USE
Squeeze-Measure-Pour System
(33.8 fl oz/1 L Bottle with 50 mL Metering Cup)
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

When body weight is between markings, use the higher corrected body weight with the pointer on the knurled cap. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

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HOW TO USE
Squeeze-Measure-Pour System
(8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

HOW TO USE
Squeeze-Measure-Pour System
(33.8 fl oz/1 L Bottle with 50 mL Metering Cup)
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

When body weight is between markings, use the higher corrected body weight with the pointer on the knurled cap. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. Attach the metering cup to the bottle.

Front Side
of LeafletInside
of Leaflet

2 3/8"

2 3/8"

2 1/2"

Product 41310A

100 mg (1.00 g) (1 L)

Contains 5.00 g ivermectin/mL

pour-on for cattle

(ivermectin)

Ivomec

Ivomec[®]

(ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis and control of parasitism.

INDICATIONS

For the treatment and control of external and internal parasites including: Ootidagry, botfly, hornworms, or fly, horn flies, and biting lice and sarcoptic mange. For more information, see package insert for complete directions.

DOSEAGE

The dose rate is 1 mL for each 200 lb of body weight. It should be applied along the top of the neck and down the back of the tailhead.

ADMINISTRATION

Attach the dosing cup (see diagram) to the top of the bottle. Set the dose by turning the top of the dosing cup until the weight in the pointer on the knurled cap. When dosing, use the markings on the dosing cup.

Hold the bottle upright and squeeze it to deliver the required dose as indicated by the markings on the dosing cup.

By releasing the pressure, the dosing cup will return to its original position. To the bottle to deliver the dose. When 22.5 lb of body weight dose is required, turn the pointer to "STOP". Before dosing, the cap will be in the "STOP" position and dose the system will be set.



100 mg (1.00 g) (1 L)
5.00 g ivermectin/mL

100 mg (1.00 g) (1 L)
5.00 g ivermectin/mL



100145100

100145100
Code 128 0-126
Height 1.18
Height 1.2
Only Read

CGY Component 1030-1451-00

Colors:
Use PANTONE MATCHING SYSTEM
FOR ACCURATE COLOR REPRESENTATIONS

	PMS 874 Gold
	Special Brown (c=0,m=74,y=100,k=53)
	Black
	White
	Magenta
	Yellow
	PMS 185 Red

Mailed Unfolded
2020 Standard Size
March 20, 2000, U.S.A.



Product 41310A

tec
(in)

for cattle
ectin/mL

Stomach Worm),
Biting Lice, Biting Lice.

Ivomec
(ivermectin)
pour-on for cattle

This topically applied formulation of IVOQUEC® (ivermectin) delivers internal and external parasite control in one convenient, low-volume application.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect contents from light.

Use only in well-ventilated areas
or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected
to wet cattle within six hours after
treatment.

This product is for application to skin surfaces only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when MONTEC Pear-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange soaks or lesions, or with dermatoses or adherent materials, e.g. oiled mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

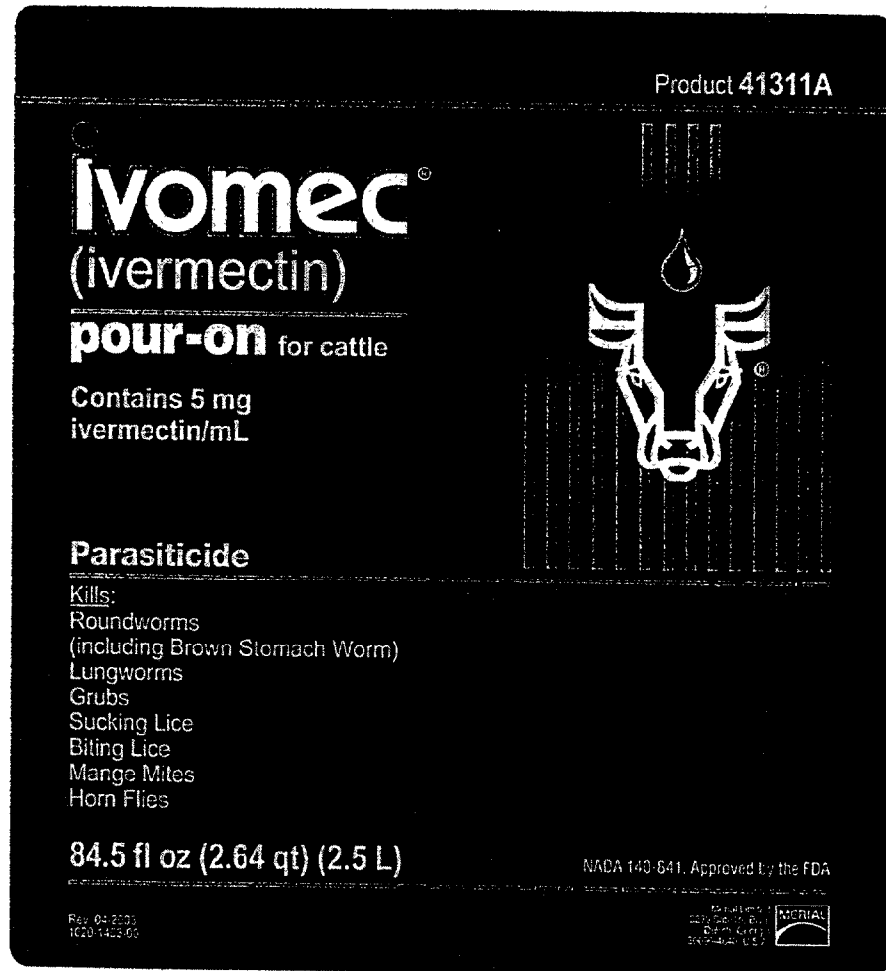


Barcode Pro 40 UPC-A
Symbol Width: 2.45
Placed Magnification: 100%
Bar X-Dimension: 0.25
Width: 1-1/4"
Height: 1"
Color: Black

A

5 3/4"

6 1/4"



Cyan does NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY		Component # 1020-1453-00
Client: <u>Ruminant Animal Global Enterprise</u>	Graphic Designer: <u>Chandra Bulmer</u>	Colors: Use PANTONE MATCHING SYSTEM for an accurate color representation. <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: black; margin-right: 5px;"></div> <div>PMS 874 Gold</div> </div> <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: brown; margin-right: 5px;"></div> <div>Special Brown (c=0/m=74/y=100/k=80)</div> </div> <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: magenta; margin-right: 5px;"></div> <div>Magenta</div> </div> <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: yellow; margin-right: 5px;"></div> <div>Yellow</div> </div>
Originator: <u>Tanya Porcha</u>	Telephone #: <u>678-638-3261</u>	
Country: <u>USA</u>	Date: <u>13 June 2003</u>	
Brand: <u>Ivomec Pour-On</u>	Revision - Date: A - 03/07/03	
Project: <u>2.5 Liter</u>	Note: this revision B - 04/04/03 history is for internal C - 04/15/03 PRD GPT purposes ONLY D - 06/13/03 Revised PRD	
Component Description: <u>Label - Front</u>		Merial Limited 3239 Satellite Blvd. Duluth, GA 30096, U.S.A.

5 3/4"

6 1/4"

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING

NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Lot No & Exp Date ▼

U.S. Pat. 4,199,569

Made in U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Unvarnished Area
1-1/2"W x 1"H

84.5 fl oz (2.64 qt) (2.5 L)

Rev. 04-2003
1020-1454-00

Cyan does NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # **1020-1454-00**

Client: Ruminant Animal Global Enterprise

Originator: Tanya Porcha

Country: USA

Brand: Ivomec Pour-On

Project: 2.5 Liter

Component Description: Label - Back

Graphic Designer: Chandra Bulmer

Telephone #: 678-638-3261

Date: 15 April 2003

Revision - Date: A - 03/07/03

Note: this revision B - 03/26/03

history is for internal C - 04/15/03 PRD

GPT purposes ONLY

Colors:

Use **PANTONE MATCHING SYSTEM**
for an accurate color representation.



Special Brown (c=0/m=74/y=100/k=80)

PMS 185 Red

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.



Ivomec[®]
(ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

84.5 fl oz (2.64 qt) (2.5 L)

Product 41311A

Product 41311A

Ivomec[®]
(ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm),
Lungworms, Grubs, Sucking Lice, Biting Lice,
Mange Mites, Horn Flies

Contains 100-550 lb Doses



NADA 140-841 Approved by the FDA

84.5 fl oz (2.64 qt) (2.5 L)



Ivomec[®]
(ivermectin)

pour-on for cattle

This topically applied formulation of IVOMEC[®] (ivermectin) delivers internal and external parasite control in one convenient low-volume application.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect contents from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use. Cattle should not be treated when hair or hide is wet, since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.



Barcode P1111A JPC 6
Symbol Width 1.45
Placed Magnification 100%
Bar Dimension 025
Width 1.45
Height 11
Cale 020

Cyan does NOT Print!

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # 1030-1455-00

Client: **Ruminant Animal Global Enterprise**
Originator: **Tamara Porcha**
Country: **USA**
Brand: **Ivomec Pour-On**
Project: **2.5 Liter**
Component Description: **Teck Carton**

Graphic Designer: **Chandra Bulmer**
Telephone #: **878-638-3261**
Date: **13 June 2003**
Revision - Date: **8-00/000**
100% PMS 874 Gold
100% PMS 874 Gold
100% PMS 874 Gold
100% PMS 874 Gold

Colors:
Low MANTHE MATCHING SYSTEM
PMS 874 Gold
Special brown (P-200-7-1) (50%+50%)
Black
Magenta
Yellow
PMS 185 Red

Ivomec[®] (ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Connect the applicator gun to the collapsible pack as follows:

Attach the open end of the draw-off tubing to the dosing equipment (Because of the solvents used in the formulation, only the Protector Branch Gun from Instrument Supplies Limited or equivalent is recommended. Other applicators may exhibit compatibility problems, resulting in leaking, incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Branch Gun, the gun and tubing must not be washed.



WILMINGTON, DE
BRIDGEVILLE, PA
KANSAS CITY, MO



LOT 1030-1455-00

Ivomec[®] (ivermectin)

pour-on for cattle

Animal Safety

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING
NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

RESIDUE INFORMATION:
Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Rev. 04/2003
1030-1455-00

Ivomec[®] (ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

84.5 fl oz (2.64 qt) (2.5 L)

Product 41311

Product 41311

Ivomec[®] (ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worms), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 100-550 lb Doses



NADA 140-811 Approved

84.5 fl oz (2.64 qt) (2.5 L)

Cyan does NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY		Component # 1030-1455-00
Client: Ruminant Animal Global Enterprises	Graphic Designer: Chandra Bulmer	Colors: CMYK PANTONE 4240 C, 5724 M, 674 Y, 674 K
Originator: Tandy Porche	Telephone #: 571-528-3261	Specialty: PMS 674 Gold
Country: USA	Date: 3 June 2003	Specialty: Black
Brand: Ivomec Pour-On	Revision: Data A	Specialty: Magenta
Project: 2.5.1.8w	Revision: Data B	Specialty: Yellow
Component Description: Tack Card	Revision: Data C	Specialty: PMS 65 Red
	Revision: Data D	
	Revision: Data E	

Ivomec

(ivermectin)

pour-on for cattle

Ivomec

(ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

DOSE

The dose rate is 1 ml for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Connect the applicator gun to the collapsible pack as follows:

Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in leaking, incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is 12 hours, disconnect the gun and draw-off tubing from the product container, and empty the product from the gun and tubing back into the product container. To prevent removal of essential lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

Studies have demonstrated the safety of ivermectin. Based on the typical application rate, ivermectin is expected to be safe for the treatment of subclinical parasitism.

NOT FOR SALE
Keep away from heat, sparks, open flame and other sources of ignition.

This product is not for sale in the United States. It is not for use in humans. It is not for use in horses. It is not for use in dogs. It is not for use in cats. It is not for use in birds. It is not for use in fish. It is not for use in reptiles. It is not for use in amphibians. It is not for use in invertebrates. It is not for use in plants. It is not for use in animals.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION.

MERIAL



Merck & Co., Inc.

Kenilworth, NJ 07033

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Printed in the USA.

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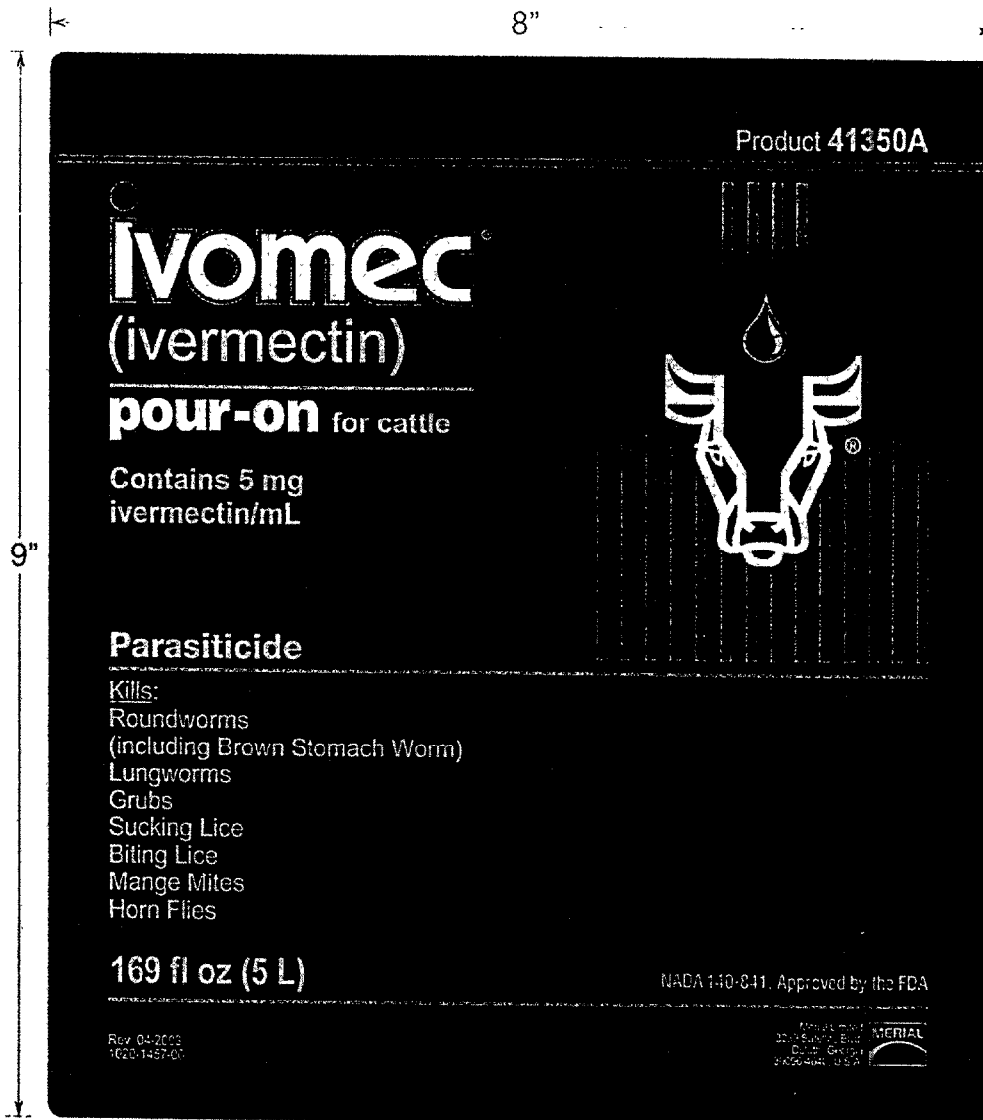
1030-1455-00

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1030-1455-00



Dieline for Merial 5L Front and Back Labels
Final Label size is 8" x 9" Created 12/02

Cyan does NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY		Component = 1020-1457-00
Client: Ruminant Animal Global Enterprise	Graphic Designer: Chandra Bulmer	Colors: Use PANTONE MATCHING SYSTEM for an accurate color representation. PMS 874 Gold Special Brown (c=0/m=74/y=100k=80) Magenta Yellow
Originator: Tanya Porcha	Telephone #: 678-638-3261	
Country: USA	Date: 13 June 2003	
Brand: Ivomec Pour-On	Revision - Date: A - 03/07/03 B - 04/04/03 C - 04/15/03 PRD D - 06/13/03 Revised PRD	
Project: 5 L	Note: this revision history is for internal GPI purposes ONLY	
Component Description: Label (front)		Merial Limited 2329 Satellite Blvd. Duluth, GA 30096, U.S.A.

8"

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING

NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

U.S. Pat. 4,199,569

Made in U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Lot No & Exp Date ▼

Unvarnished Area
1-1/2"W x 1"H

169 fl oz (5 L)

Rev. 04-2003
1020-1458-00

Dieline for Merial 5L Front and Back Labels
Final Label size is 8" x 9" Created 12/02

Cyan does NOT print.

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # 1020-1458-00

Client: Ruminant Animal Global Enterprise
Originator: Tanya Porcha
Country: USA
Brand: Ivomec Pour-On
Project: 5 L

Graphic Designer: Chandra Bulmer
Telephone #: 678-638-3261
Date: 15 April 2003
Revision - Date: A - 03/07/03
Note: this revision is for internal history only
GPI requires DML

Colors:

Use PANTONE MATCHING SYSTEM for an accurate color representation.

Special Brown (c=0/m=74/y=100/k=80)
PMS 185 Red

Component Description: Label (back)

Merial Limited
3220 Sabal Trail Blvd.
Duluth, GA 30096, U.S.A.

Cyan does NOT Print!

MERIAL GLOBAL PACKAGING TECHNOLOGY		1030-1459-00
Client: Parke-Davis International	Graphic Designer: Chandra Sathya	Colors:
Originator: Tamara Zwick	Telephone #: 612-436-3211	100% PMS 100 Yellow
Country: USA	Date: 12 April 2005	100% PMS 100 Yellow
Brand: Ivomec Pour-On	Graphic: 100% PMS 100 Yellow	100% PMS 100 Yellow
Product: 1.1 Liter	Graphic: 100% PMS 100 Yellow	100% PMS 100 Yellow
Component Description: Pack Carton	Graphic: 100% PMS 100 Yellow	100% PMS 100 Yellow

Product 41350A

Ivomec

(ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 200-550 lb Doses



ALL INFORMATION ON THIS PRODUCT IS FOR INFORMATIONAL PURPOSES ONLY. IT IS NOT A SUBSTITUTE FOR A VETERINARIAN'S ADVICE.

169 fl oz (5 L)



Ivomec

(ivermectin)

pour-on for cattle

This topically applied formulation of IVOMEC® (ivermectin) controls internal and external parasite control in one convenient low-volume application.

PRECAUTIONS

Store away from excessive heat (105 F/40 C) and protect contents from light.

Use only in well-ventilated areas outdoors.

Close container tightly when not in use.

Cattle should not be fed for 24 hours after application. Do not use when rain is expected to wash off within 24 hours after treatment.

The product is for application to skin surface only. Do not ingest or use internally.

Cloudiness in the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32 F. Above 150 F, the room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to spots of the skin with major scabs or lesions or wet dermatitis or oedematous materials (e.g., insecticide residues).

Ivermectin has been associated with adverse reactions in horses (e.g., incoordination). IVOMEC Pour-On is not recommended for use in horses other than ponies.

Do not contaminate water by direct application or by the improper disposal of empty containers. Dispose of containers in an approved landfill by incineration.



For more information, contact your local Merial representative or call 1-800-828-6888.

Product 41350A
169 fl oz (5 L)
Contains 5 mg ivermectin/mL
pour-on for cattle
(ivermectin)
Ivomec

Ivomec
(ivermectin)
pour-on for cattle

For use under the supervision of a veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS
Treatment and control of gastrointestinal roundworms (including whitehead), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange in cattle.

Apply 1 mL for each 22 lb of body weight. The formulation should be applied along the backbone, extending from the withers to the hindquarters.

APPLICATION
Apply the applicator gun to the collapsible pack as follows:
1. Insert the applicator gun into the dosing equipment. Because of the solvent used in this product, the applicator gun may exhibit condensation, resulting in a leaking applicator gun. To prevent this, the applicator gun should be kept dry.
2. Push the applicator gun into the dosing equipment and tighten down. After the applicator gun is in place, push the applicator gun, checking for leaks.
3. Follow the manufacturer's directions for adjusting the dose.
4. The interval between uses of the applicator gun is expected to exceed 12 hours. If the applicator gun is used more frequently, the product should not be applied more than once from the applicator gun. To prevent removal of product from the applicator gun, the applicator gun and tubing must not be washed.

Ivomec
(ivermectin)
pour-on for cattle

Animal Safety
Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be as safe as well tolerated by breeding animals as to the subcutaneous formulation which had no effect on breeding performance.

WARNING
NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

This product should not be applied to humans because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental exposure, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION

RESIDUE INFORMATION: Cattle may not be used within 48 days of application for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for the product in pre-ruminant calves. Do not use in calves to be processed for veal.

Cyan does NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY		1030-1459-00
Client: Roche Animal Health Europe	Graphic Designer: Cherise Palmer	Colors: CMYK
Operator: Tanya Pardo	Telephone: 617-438-1201	Color: CMYK
Country: USA	Date: 12/04/2003	Special: None
Brand: Roche/Cherise	Version: 1.0	Black: None
Project: 1.0	Color: CMYK	Magenta: None
Component: Disc/Print	Color: CMYK	Yellow: None
		Color: CMYK

Product 41350A

Ivomec
(ivermectin)
pour-on for cattle
Contains 5 mg ivermectin/mL

Parasiticide
Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies
Contains 200-550 lb Doses



169 fl oz (5 L)

Ivomec
(ivermectin)

for cattle
contains 5 mg ivermectin/mL
Product 41350A

Ivomec
(ivermectin)
 for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitic

INDICATIONS

For the treatment and control of gastro-intestinal roundworms (including ascarids), lungworms, grubs, horn flies, sucking and biting lice and ear ticks (including ear mites). See package insert for complete indications and use directions.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied topically in a narrow strip extending from the withers to the tail head.

ADMINISTRATION

Connect the applicator gun to the collapsible pour-on tube.
After the opening of the draw-off tubing, the drawing equipment. Because of the formulation, only the Predator Drench Gun from Merial is recommended. Other applicators may cause or contribute to problems resulting in dosage or leakage.

Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the cap.

Gently pump the applicator gun, checking for leaks.

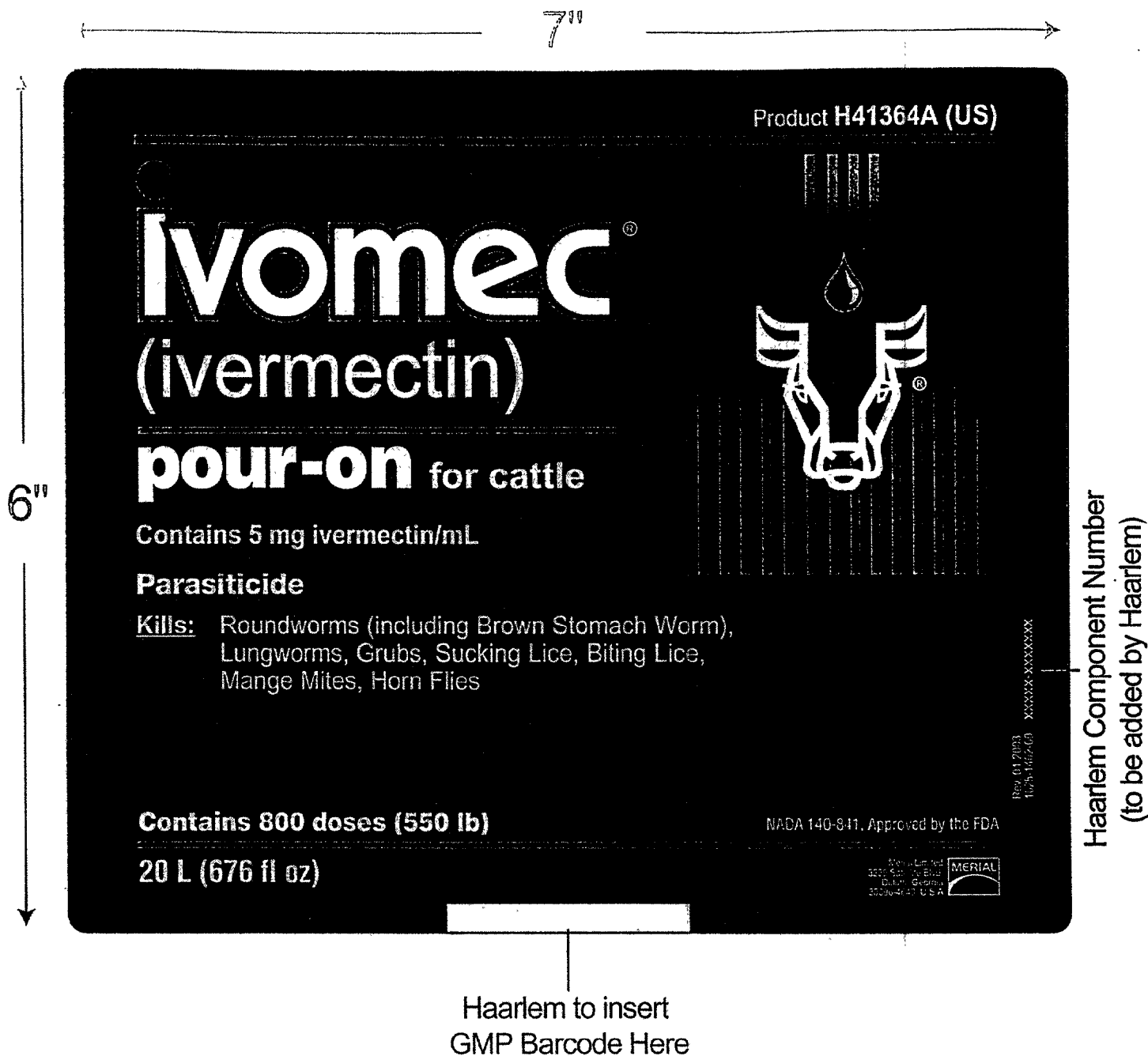
Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the applicator and empty the product from the gun and tubing back into the product container. Do not remove or replace tubing from the Predator Drench Gun; the gun and tubing must not be washed.




Merial
10000
10000
10000





Note: Cyan does NOT Print

MERIAL GLOBAL PACKAGING TECHNOLOGY		Component # <u>1025-1462-00</u>
Client: <u>Ruminant Animal Global Enterprise</u>	Graphic Designer: <u>Chandra Bulmer</u>	Colors: <i>Use PANTONE MATCHING SYSTEM for an accurate color representation.</i> <div><div></div> PMS 874 Gold <div></div> Special Brown (c=0/m=74/y=100/k=80) <div></div> Magenta <div></div> Yellow</div>
Originator: <u>Tanya Porcha</u>	Telephone #: <u>678-638-3261</u>	
Country: <u>USA</u>	Date: <u>13 June 2003</u>	
Brand: <u>Ivomec Pour-On</u>	Revision - Date: A - 03/10/03	
Project: <u>20 Liter</u>	<i>Note: this revision</i> B - 03/25/03	
	<i>history is for internal</i> C - 04/15/03 PRD	
		<i>GPT purposes ONLY</i> D - 06/13/03 Revised PRD
Component Description: <u>Shipper Label - Front</u>		Merial Limited 3239 Satellite Blvd. Duluth, GA 30096, U.S.A. 

Note: Cyan does NOT print.

7"

ivomec®
(ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with IVOMEC® (ivermectin) Pour-On. Other dosing equipment may be incompatible, resulting in locking, incorrect dosage and leakage. Follow the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Connect the dosing applicator and the draw-off tubing to the container as follows:

Attach the open end of the draw-off tubing to an appropriate dosing applicator. Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap having the draw-off tubing. Gently prime the dosing applicator, checking for leaks.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME,
AND OTHER SOURCES OF IGNITION

Product H41364A (US)

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

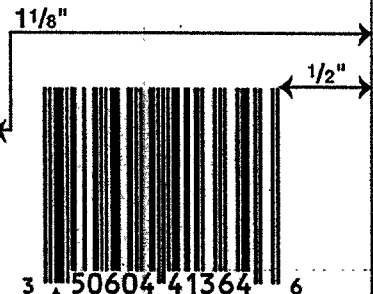
Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

6 1/8"

Lot No.:

No Varnish Area:
1" x 3/4"

Exp Date:



U.S. Pat. 4,199,569

Made in the Netherlands

IVOMEC and Cattle Head Logo are registered
trademarks of Merial Limited.

Rev. 04-2003
1020-1463-00

xxxxxx/xxxxxxX

Place GMP
Barcode Here

Haarlem to insert
GMP Barcode Here

Haarlem Component Number
(to be added by Haarlem)

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # **1020-1463-00**

Client: Ruminant Animal Global Enterprise

Originator: Tanyla Porcha

Country: USA

Brand: Ivomec Pour-On

Project: 20 Liter (Merialization)

Component Description: Shipper Label - Back

Graphic Designer: Chandra Bulmer

Telephone #: 678-638-3261

Date: 15 April 2003

Revision - Date: A - 03/07/03

Note: this revision B - 03/26/03

history is for internal C - 04/15/03 PRD

GPT purposes ONLY

Colors:

Use **PANTONE MATCHING SYSTEM**
for an accurate color representation.

Special Brown (c=0/m=74/y=100/k=80)

PMS 185 (red)

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.



6 1/16"

6 1/4"

Product H41364A (US)

Ivomec[®]
(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

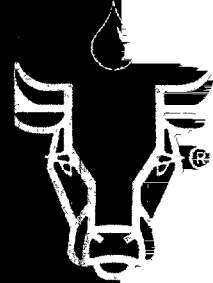
Kills:

Roundworms
(including Brown Stomach Worm)
Lungworms
Grubs
Sucking Lice
Biting Lice
Mange Mites
Horn Flies

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

20 L (676 fl oz)

1000-1461 OF



WARNING! FLAMMABLE.
KEEP AWAY FROM HEAT
SPARKS, OPEN FLAME AND
OTHER SOURCES OF IGNITION.

WARNING-
NOT FOR USE IN EU

Lot No.:

Exp Date:

NADA 140-841, Approved by the

Merck & Co., Inc.
3000 State College
Duluth, Georgia
30090-2000, U.S.A.

Outsert Front Cover

Haarlem
GMP Bar

6 1/16"

Product **H41364A (US)**

Ivomec
(ectin)
n for cattle



WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT,
SPARKS, OPEN FLAME, AND
OTHER SOURCES OF IGNITION.

WARNING
NOT FOR USE IN HUMANS.

Lot No.:

Exp Date:



XXXXXXXXXX

NADA 140-841, Approved by the FDA

Merial Limited
3200 Sabalwood
Duluth, Georgia
30090-4640, U.S.A.



LIFT

MERIAL GLOBAL PACKAGING

Client: Ruminant Animal Global Enterprise

Originator: Bruce Somerville

Country: USA

Brand: Ivomec Pour-On

Project: 20 Liter (Revise Persistent Activity)

Component Description: Outsert

Graphic Design

Telephone #:

Date: 18 Aug

Revision - Dat

Note: this revision
history is for internal
GPT purposes ONLY

Haarlem Component Number
(to be added by Haarlem)

tsert Front Cover

Haarlem to insert
GMP Barcode Here

Facsimile Labeling

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # **1020-1461-OF**

Client: Ruminant Animal Global Enterprise

Originator: Bruce Somerville

Country: USA

Brand: Ivomec Pour-On

Project: 20 Liter (Revise Persistent Activity)

Component Description: Outsert

Graphic Designer: Patricia Greene

Telephone #: 678-638-3302






Date: 18 August 2003

Revision - Date: A - 03/28/03

Note: this revision B - 03/28/03 (SM)
history is for internal C - 08/18/03 (PG)
GPT purposes ONLY

Colors:

*Use PANTONE MATCHING SYSTEM
for an accurate color representation.*

 PMS 874 Gold
 Special Brown (c=0/m=74/y=100/k=80)
 Black
 Magenta
 Yellow

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096, U.S.A.



1020-1461-OF (to be added by Haarlem)

sert
Here

ivomec[®]

(ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INTRODUCTION

IVOMEC (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

INDICATIONS

IVOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the treatment and control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i>	(adults and L ₄)
(including inhibited stage)	
<i>Haemonchus placei</i>	(adults and L ₄)
<i>Trichostrongylus axei</i>	(adults and L ₄)
<i>T. colubriformis</i>	(adults and L ₄)

<i>Cooperia oncophora</i>	(adults and L ₄)
<i>Cooperia punctata</i>	(adults and L ₄)
<i>Cooperia sumabada</i>	(adults and L ₄)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>Trichuris</i> spp.	(adults)

Lungworms	
<i>Dictyocaulus viviparus</i>	(adults and L ₄)
Cattle Grubs	(parasitic stages)
<i>Hypoderma bovis</i>	
<i>H. lineatum</i>	

Mites	
<i>Sarcoptes scabiei</i> var. <i>bovis</i>	

Lice	
<i>Linognathus vituli</i>	
<i>Haematopinus eurysternus</i>	
<i>Damalinia bovis</i>	
<i>Solenopotes capillatus</i>	

Horn Flies	
<i>Haematobia irritans</i>	

Persistent Activity

IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia sumabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Squeeze-Measure-Pour System
(8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)
Attach the metering cup to the bottle.

Set the dose by align the correct knurled cap markings, use the slight excess of calibration lines

By releasing the cap, it adjusts to the correct dose. The off-center line between dosing

Squeeze-Meas
(33.8 fl oz/1 L)

Attach the metering cup to the bottle

Set the dose by align the correct knurled cap. When using the higher setting, use the slight excess of calibration lines

By releasing the cap, it adjusts to the correct dose. When 220 required, turn the cap to the dose. The system between

Collapsible Pa
(84.5 fl oz/2.5 L)

Connect the appropriate tubing as follows:

Attach the open end of the dosing equipment in the horn gun from Instrum is recommended compatibility of dosage or leakage. Replace the shipping cap and tighten down. At cap.

Gently prime the system. Follow the manual dose.

When the interval is expected to be 10 and draw-off tubing

Outsert Page 1
(inside front cover)



For assistance in the control of parasitism.

IVOME Pour-On delivers internal and external parasites and is developed by scientists at the University of Florida, Gainesville, Florida.

The macrocyclic lactone class is a unique mode of action. It is selective and with high chloride ion channels which and muscle cells.

In the permeability of the cell with hyperpolarization of the membrane in paralysis and death of the parasite. This class may also interact with ion channels, such as those for gamma-aminobutyric acid.

Compounds of this class is active in mammals do not have ion channels, the macrocyclic lactone for other mammalian ligand and they do not readily cross the blood-brain barrier.

At the recommended dose rate for the treatment and control of the following parasites:

- Adults and L₄
- Adults and L₄
- Adults and L₄
- Adults and L₄

Cooperia oncophora (adults and L₄)
Cooperia punctata (adults and L₄)
Cooperia sumabada (adults and L₄)
Strongyloides papillosus (adults)
Oesophagostomum radiatum (adults and L₄)
Trichuris spp. (adults)
Lungworms
Dictyocaulus viviparus (adults and L₄)
Cattle Grubs (parasitic stages)
Hypoderma bovis
H. lineatum
Mites
Sarcoptes scabiei var. *bovis*
Lice
Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus
Horn Flies
Haematobia irritans
Persistent Activity
IVOME Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia sumabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.
Treatment of Cattle for Horn Flies
IVOME Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOME Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.
DOSAGE
The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.
ADMINISTRATION
Squeeze-Measure-Pour System
(8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)
Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.
Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.
By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.
Squeeze-Measure-Pour System
(33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)
Attach the metering cup to the bottle.
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.
Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.
By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 lb (10 mL) or 330 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.
Collapsible Pack
(84.5 fl oz/2.5 L Pack and 169 fl oz/5 L Pack)
Connect the applicator gun to the collapsible pack as follows:
Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage.)
Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.
Gently prime the applicator gun, checking for leaks. Follow the manufacturer's directions for adjusting the dose.
When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and

empty the product from the gun the product container. To prevent lubricants from the Protector I and tubing must not be washed.
20 Liter Pack
(676 fl oz/20 L Pack)
Use dosing equipment (applicator with stem) compatible with IVOME Pour-On. Other dosing equipment is incompatible, resulting in lock and leakage. Follow the manufacturer's directions for proper use and maintenance of the dosing equipment.
Connect the dosing applicator to the container as follows:
Attach the open end of the dosing equipment to the container. Connect the dosing applicator tubing to the cap with the shipping cap with the cap tubing. Gently prime the tubing, checking for leaks.
When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and replace the shipping cap.
ANIMAL SAFETY
Studies conducted in the U.S.A. show the safety margin for ivermectin levels, the topically applied form, to be at least as well-tolerated by cattle as the subcutaneous formulation on breeding performance.
WARNING
NOT FOR USE IN HUMANS
Keep this and all drugs out of the reach of children.
The Material Safety Data Sheet (MSDS) is available upon request. For detailed occupational safety information, effects, obtain an MSDS or for assistance call 1-888-637-4251.
WARNING! FLAMMABLE
KEEP AWAY FROM HEAT, SPARKS AND OTHER SOURCES
This product should not be applied to the face because it may be irritating to the eyes and absorbed through the skin.

57/16"

turning the top section of the cup to body weight with the pointer on the When body weight is between a higher setting.

upright and squeeze it to deliver a required dose as indicated by the

pressure, the dose automatically ect level. Tilt the bottle to deliver the (OP) position will close the system

re-Pour System

Bottle with 50 mL Metering Cup)

ing cup to the bottle.

turning the top section of the cup to body weight with the pointer on the n body weight is between markings, tting.

upright and squeeze it to deliver a required dose as indicated by the

pressure, the dose automatically ect level. Tilt the bottle to deliver the b (10 mL) or 330 lb (15 mL) dose is pointer to "STOP" before delivering ff (STOP) position will close the dosing.

k Pack and 169 fl oz/5 L Pack) --- licator gun to the collapsible pack

i end of the draw-off tubing to ment. (Because of the solvents ulation, only the Protector Drench ent Supplies Limited, or equivalent, l. Other applicators may exhibit lems resulting in locking, incorrect e.)

ing cap with the draw-off cap and ach draw-off tubing to the draw-off

applicator gun, checking for leaks. icturer's directions for adjusting the

between uses of the applicator gun eed 12 hours, disconnect the gun g from the product container and

empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

20 Liter Pack (676 fl oz/20 L Pack)

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with IVOMEC® (ivermectin) Pour-On. Other dosing equipment may be incompatible, resulting in locking, incorrect dosage and leakage. Follow the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Connect the dosing applicator and the draw-off tubing to the container as follows:

Attach the open end of the draw-off tubing to an appropriate dosing applicator. Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap having the draw-off tubing. Gently prime the dosing applicator, checking for leaks.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING

NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Meril at 1-888-637-4251.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize

Facsimile Labeling

1 1/16"

5 1/8"

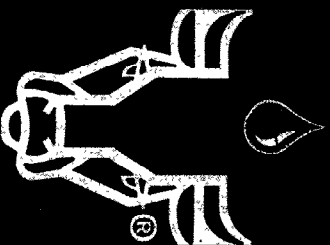
9/16"

Product H41364A (US)

Ivomec
(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL



Parasiticide

Kills:

Roundworms
(including Brown Stomach Worm)
Lungworms
Grubs
Sucking Lice
Biting Lice
Mange Mites
Horn Flies

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT,
SPARKS, OPEN FLAME, AND
OTHER SOURCES OF IGNITION.

WARNING
NOT FOR USE IN HUMANS.
Do not contaminate water by direct
application or by the improper
disposal of drug containers. Dispose
of containers in an approved landfill
or by incineration.

20 L (676 fl oz)

MADA 140-841, Approved by the FDA

1000-1461-0F

Manufactured by
Merial Limited
Duluth, GA 30036
36036-4540 U.S.A.



No Print/Glue Area 1 1/16" w x 6 1/4" h

No Print/Glue Area 9/16" w x 6 1/4" h

Outsert Base

Haarlem Component Number
(to be added by Haarlem)

3" 5/16"

Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety
Studies indicate that when ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED
IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 fl oz/2.5 L or 169 oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Merial Limited
3238 Satellite Blvd.
Duluth, Georgia
30096-4640, U.S.A.

Merial Limited, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domesticated in Delaware, USA as Merial LLC.

U.S. Pat 4,199,569
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Made in the Netherlands
Rev. 08-2003

No Print/Glue Area 5/16" w x 6 1/4" h

6 1/4"

No Print/Glue Area 1 1/16" w x 6 1/4" h

1 1/16" 6 3/4" 5 1/8"

Ivomec

(ivermectin)

pour-on for cattle

Contains 5 mL ivermectin/mL

Parasiticide

- Kills:
 - Roundworms (including Brown Stomach Worm)
 - Lungworms
 - Grubs
 - Sucking Lice
 - Biting Lice
 - Mange Mites
 - Horn Flies

WAR
KEEP
SPARK
OTHER E

20 L (676 fl oz)

5/16"

5 1/8"

accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS
 Store away from excessive heat (104°F/40°C) and protect from light.
 Use only in well-ventilated areas or outdoors.
 Close container tightly when not in use.
 Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.
 Do not use when rain is expected to wet cattle within six hours after treatment.
 This product is for application to skin surface only. Do not give orally or parenterally.
 Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
 Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions; or with dermatoses or adherent materials, e.g., caked mud or manure.
 Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs
 IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions.

Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety
 Studies indicate that when ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED
 IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 fl oz/2.5 L or 169 fl oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

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 Duluth, Georgia
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Merial Limited, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domesticated in Delaware, USA as Merial LLC.

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6 1/4"

6 1/4"

No Print/Glue Area 5/16" w x 6 1/4" h

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